Notice of Allowability	Application No.	Applicant(s)	
	10/663,577	DENNIS ET AL.	
	Examiner	Art Unit	
	Tiffany M. Gough	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *interview with Stephanie Mansfield on 11/9/2007*.

2. ☒ The allowed claim(s) is/are *1,3-21,23-29 and 32-40*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. (currently amended) A system for forming a cardiac muscle construct, comprising: cardiac cells cultured *in vitro* on a substrate to form a cardiac muscle construct without an exogenous scaffold material in a contractile region thereof, wherein at least some of the cells are in contact with and attached to at least two anchors secured to the substrate in a spaced relationship, said cells form a confluent monolayer between the anchors and detach from the substrate to form a self-organizing three-dimensional cardiac muscle construct.

~~a substrate;~~
~~at least two anchors secured to the substrate in spaced relationship;~~
~~and~~
~~cardiac cells provided on the substrate~~ to form a cardiac muscle construct
~~without an exogenous scaffold material~~ in a contractile region thereof, ~~wherein only at least some of the cells are in contact with the anchors~~ and attach thereto,
~~the cardiac cells cultured in vitro, wherein the anchors are receptive to the cells and allow the cells to attach thereto and to form a confluent monolayer between the anchors. the substrate configured to permit the monolayer to detach which subsequently detaches from the substrate and self-organize self-organizes to form ~t the three-dimensional cardiac muscle construct.~~

2. (canceled)
3. (original) The system according to claim 1, wherein the cardiac cells include cardiac myocytes.
4. (original) The system according to claim 1, wherein the cardiac cells include fibroblasts.
5. (original) The system according to claim 1, wherein the cardiac muscle construct is spontaneously contractile.
6. (original) The system according to claim 1, wherein the cardiac muscle construct is responsive to electrical stimuli.
7. (original) The system according to claim 1, wherein the cardiac muscle construct is responsive to chemical stimuli.
8. (original) The system according to claim 1, wherein the cardiac muscle construct is resistant to fatigue.
9. (canceled)
10. (previously presented) The system according to claim 1, wherein the anchors include silk suture segments coated with cell adhesion molecules.
11. (original) The system according to claim 10, wherein the cell adhesion molecules include laminin.
12. (original) The system according to claim 1, wherein the substrate is coated with cell adhesion molecules.
13. (original) The system according to claim 12, wherein the cell adhesion molecules include laminin.
14. (original) The system according to claim 13, wherein the concentration of laminin is about 0.4 to 2.0 #g/cm2.
15. (original) The system according to claim 1, wherein the cardiac muscle construct is substantially cylindrical.

16. (original) The system according to claim 1, further comprising skeletal muscle cells cultured in combination with the cardiac cells.
17. (currently amended) A method for forming a cardiac muscle construct, comprising: culturing cardiac cells *in vitro* on a substrate to form a cardiac muscle construct without an exogenous scaffold material in a contractile region thereof, wherein at least some of the cells are in contact with and attached to at least two anchors secured to the substrate in a spaced relationship, said cells form a confluent monolayer between the anchors and detach from the substrate to form a self-organizing three-dimensional cardiac muscle construct.

~~providing a substrate;~~
~~securing at least two anchors to the substrate in spaced relationship;~~
~~providing cardiac cells on the substrate to form a cardiac muscle construct without an exogenous scaffold material in a contractile region thereof, wherein only at least some of the cells are in contact with the anchors and attach thereto; and culturing the cardiac cells in vitro, wherein the anchors are receptive to the cells and allow the cells to attach thereto to form a confluent monolayer between the anchors, the substrate configured to permit the monolayer to detach which subsequently detaches from the substrate and self-organize self- organizes to form a the three-dimensional cardiac muscle construct.~~
18. (original) The method according to claim 17, wherein providing cardiac cells includes providing cardiac myocytes.
19. (original) The method according to claim 17, wherein providing cardiac cells includes providing fibroblasts.
20. (original) The method according to claim 17, further comprising eliciting a response of the cardiac muscle construct to electrical stimuli.
21. (previously presented) The method according to claim 17, further comprising eliciting a response of the cardiac muscle construct to chemical stimuli.
22. (canceled)
23. (previously presented) The method according to claim 17, wherein the anchors include silk suture segments coated with cell adhesion molecules.
24. (original) The method according to claim 23, wherein the cell adhesion molecules include laminin.
25. (original) The method according to claim 17, further comprising coating the substrate with cell adhesion molecules.
26. (original) The method according to claim 25, wherein the cell adhesion molecules include laminin.
27. (original) The method according to claim 26, wherein the concentration of laminin is about 0.4 to 2.0/~g/cm2.
28. (original) The method according to claim 17, further comprising the step of measuring a passive or active force ~~functional property~~ of the cardiac muscle construct and then using the measured force ~~property as feedback~~ to control the further formation of the cardiac muscle construct.
29. (original) The method according to claim 17, further comprising culturing skeletal muscle cells in combination with the cardiac cells.
~~30. (previously presented) The method according to claim 17, further including implanting the cardiac muscle construct in a recipient.~~
~~31. (original) The method according to claim 17, further including wrapping an acellularized aorta with a layer of cardiac cells.~~
32. (currently amended) A cardiac muscle construct, comprising: cardiac myocytes provided on a substrate to form a cardiac muscle construct without an exogenous scaffold material in a contractile region thereof, wherein ~~only~~ at least some of the myocytes are in contact with and attach to at least two anchors secured to the substrate in spaced relationship, ~~the~~ said cardiac myocytes are cultured in vitro ~~wherein the anchors are receptive to the myocytes and allow the myocytes to attach thereto~~ to form a confluent monolayer between the anchors, and detach from the substrate to form a self-organizing three-dimensional cardiac muscle construct.
~~the substrate configured to permit the monolayer to detach which subsequently detaches from the substrate and self-organize self-organizes to form ~t the three-dimensional cardiac muscle construct.~~

33. (original) The cardiac muscle construct according to claim 32, further comprising fibroblasts provided in combination with the cardiac myocytes.
34. (original) The cardiac muscle construct according to claim 32, wherein the construct is spontaneously contractile.
35. (original) The cardiac muscle construct according to claim 32, wherein the construct is responsive to electrical stimuli.
36. (original) The cardiac muscle construct according to claim 32, wherein the construct is responsive to chemical stimuli.
37. (original) The cardiac muscle construct according to claim 32, wherein the construct is resistant to fatigue.
38. (original) The cardiac muscle construct according to claim 32, wherein the construct includes adherens junctions formed between the cardiac myocytes.
39. (original) The cardiac muscle construct according to claim 32, wherein the construct includes gap junctions between the cardiac myocytes.
40. (original) The cardiac muscle construct according to claim 32, wherein the cardiac muscle construct is substantially cylindrical.

SANDRA E. SAUCIER
PRIMARY EXAMINER